REMARKS

I. Status of the Claims

Claims 6-10 and 12-15 are pending in this application. Claims 1-5 were previously canceled by a preliminary amendment submitted June 23, 2005. Claims 11 and 16 have been canceled herein. Claim 6 has been amended by specifying that the claimed method utilizes an unmodified Sendai virus, is administered intranasally, and induces a B cell immune response to hPIV-1 infection. Support for this amendment can be found at paragraphs 0007-0011, 0021 and Examples 1 and 2 (paragraphs 0027-0080) of the published version of this application (Pub. No. 2006/0110740). Claim 12 has been amended to change dependency from canceled claim 11 to pending claim 6.

II. The Form of the Claims Has Been Corrected

On page 2 of the Office Action, the Examiner objects to claims 11-13 under 37 CFR 1.75(c) for being in improper form because claim11 fails to further limit the subject matter of claim 6 from which it depends. Claim 11 has been canceled and claim 12 has been amended to be dependent on claim 6. Reconsideration and withdrawal of this objection in view of the cancellation of claim 11 and amendment of claim 12 is respectfully requested.

III. The Claims Have Been Amended To Address the Enablement Rejection

On pages 3-6 of the Office Action, the Examiner rejects claims 6-16 under 35 U.S.C. §112, first paragraph, based on the assertion that the specification does not reasonably provide enablement for a method of protecting, enhancing immunity, or inducing a T cell immune response in a human subject against non-HPIV-1 by administering any sort of Sendai virus that has been modified in any way. Applicants respectfully traverse this rejection insofar as it may be applied to the claims as amended herein.

Applicants maintain that the specification fully enables methods for protecting, enhancing immunity and inducing both T cell and B cell immune responses in a human subject against any hPIV strain through various means of administration and assert that the Examiner has failed to carry her burden of establishing a prima facie case of nonenablement for any of these aspects of the claimed method. However, in the interest of furthering prosecution Applicants have amended the claims to align their scope with the embodiment considered by the Examiner to be enabled as described on the bottom of page 6 of the Office Action.

Reconsideration and withdrawal of this rejection in view of the amendment of the claims and remarks above is respectfully requested.

IV. Treatment of Animals Does Not Anticipate Treatment of Humans Considering the Conventional Wisdom Against Such an Extrapolation

On page 7 of the Office Action the Examiner rejects claims 6-10 and 15 under 35 U.S.C. §102 based on the assertion that the claimed method is anticipated by Hurwitz *et al.*, "Intranasal Sendai virus vaccine protects African green monkeys from infection with human parainfluenza virus-type one", *Vaccine 15(5)*: 533-540 (1997). Applicants respectfully traverse this rejection insofar as it may be applied to the claims as amended.

Hurwitz describes the administration of Sendai virus in African green monkeys. It does not describe the administration of Sendai virus in humans, although it does mention the possibility of human administration as Applicants acknowledged in the background section of the specification at paragraph 0005.

However, Applicants also point out at paragraph 0006 of the background of the specification that this possible use of Sendai virus in humans had been rejected by experts in the field due to concerns that Sendai virus may cause disease in humans and Sendai virus may not elicit cross-reactive antibodies toward human PIV-1. Skiadopolous, MH. *et al., Virology 297:* 153-160 (2002)(disclosed reference C4). This sentiment remained even after Applicants priority

date of January 20, 2003, with other investigators citing Skiadopolous favorably and remaining critical of the use of Sendai virus in humans.

For example, a 2005 review of vaccine research states that "Sendai virus . . . does not seem to be sufficiently attenuated to be used as a Jennerian vaccine in human infants". See page 5715, col. 2, first full paragraph of Girard *et. al.*, "A review of vaccine research and development: Human acute respiratory infections", *Vaccine 23*: 5708-5724 (2005). As another example, a 2006 scientific review of vaccine vectors states that "SeV replicated nearly as efficiently as wild-type HPIV1 in African green monkeys and chimpanzees, raising doubts as to whether it will be satisfactorily attenuated in unmodified form for use in sero-negative humans". See page 10302, col. 2, second full paragraph of Bukreyev *et. al.*, "Nonsegmented Negative-Strand Viruses as Vaccine Vectors", *J. Virol 80*: 10293-10305 (2006). These references have been attached to this Amendment and Response as Exhibits A and B, respectively.

Thus, the conventional wisdom at the time of the present invention was that human administration of unmodified Sendai virus to protect against hPIV infection would not work. In view of the state of the art at the time, Applicants submit that the mere mention of the possibility of human administration of Sendai virus in Hurwitz cannot be considered enabling and therefore does not anticipate the claimed method.

Reconsideration and withdrawal of this rejection in view of the amendment of the claims and remarks above is respectfully requested.

V. The Obviousness Rejection Suffers from the Same Deficiencies as the Anticipation Rejection

On page 8 of the Office Action the Examiner rejects claims 12-14 under 35 U.S.C. §103 based on the assertion that the claimed method is obvious in view of the same Hurwitz reference used to support the anticipation rejection. This rejection depends on the same assertions relied upon by the Examiner to assert anticipation and is therefore rebutted by the same arguments as

set forth above. In short, Hurwitz fails to teach or suggest the administration of Sendai virus to treat humans of any age in view of the conventional wisdom that such administration would not work.

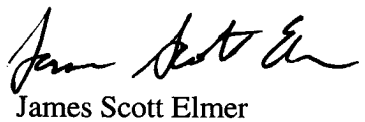
Reconsideration and withdrawal of this rejection in view of the amendment of the claims and remarks above is respectfully requested.

VI. Conclusion

In view of the amendment to the claims and the remarks above, it is believed that the Examiner may properly withdraw the objection of the claims under 37 CFR 1.75(c) and rejection of the claims under 35 U.S.C. §§102(b), 103 and 112, first paragraph.

Having now fully responded to the Office Action, Applicants respectfully submit that the present application is in condition for allowance and earnestly solicit early notice of such favorable action. No fee is believed to be required for consideration of this submission. If applicants are incorrect and a fee is required the Commissioner is hereby authorized to charge such fee to Deposit Account No. 501968.

Respectfully submitted,



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Date: October 25, 2007